GUIDELINE FOR THE EVALUATION OF UNDER TABLE FLUOROSCOPIC X-RAY EQUIPMENT

State of Utah
Department of Environmental Quality
Division of Radiation Control

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DRC Inspection Program Objective

The overall objective of the Division of Radiation Control (DRC) x-ray inspection program is to reduce the likelihood that individuals will be exposed to unnecessary radiation. In the case of registrants using x-ray equipment in the healing arts, patient exposure is of concern and proper equipment performance is essential. Registrants are required to demonstrate that the equipment satisfies the appropriate regulatory standards for calibration and performance.

Purpose of Guideline

The intent and purpose of this document is to provide users of **under table fluoroscopic x-ray equipment** guidelines for the documentation necessary to demonstrate to the DRC that the x-ray equipment satisfies the regulatory standards under clinical use conditions.

X-ray Equipment Performance and Calibration

The registrant is to document that the following requirements are met.

1) Adequate total filtration is present.
2) kVp calibration is adequate for those mA stations used during spot filming.
3) The fluoroscopy timer terminates the exposure or produces an audible signal at the end of a five minute accumulative time interval.
4) Exposures are reproducible for phototimer spot film procedures.
5) During fluoroscopy, the x-ray field collimation and alignment with the image intensifier (II) is appropriate:
  a) For both manual and automatic collimation, the maximum field is confined to the effective area of the II;
  b) For automatic collimation, the field size adjusts appropriately as the source to intensifier distance (SID) and/or the magnification mode is varied.
6) During spot filming:
  a) The x-ray field adjusts automatically to the correct portion of the film;
  b) The resulting field size is acceptable; and
  c) The center of the x-ray field aligns with the center of the film portion within the regulatory standards.
7) Fluoroscopic exposure rates do not exceed the regulatory standards.
8) Patient exposure information has been obtained for simulated clinical conditions and is posted where it is readily available to the physician during the procedure.

The following examples are presented as guidance for what will be considered an adequate evaluation, with support documentation, to demonstrate compliance:

1) Adequate Filtration

Demonstration of adequate filtration of the under table x-ray source in either the fluoroscopic or spot film mode shall be accomplished by showing that the half value layer (HVL) exceeds the minimum regulatory standard. For example, at a measured kVp value of 80, the HVL is to be equal to or greater than 2.3 mm aluminum. This can be demonstrated by:

a) Measuring the in air exposure when different thicknesses of aluminum intercept the x-ray beam and determining the HVL value; or

b) Measuring the exposure at 80 kVp with and without a 2.5 mm aluminum absorber intercepting the x-ray beam and showing that the ratio of the two exposure values exceeds 0.5.

(Documentation shall include a listing of measured exposure values and associated thicknesses of aluminum.)

2) kVp Calibration; Spot Films

Accuracy of the kVp during spot filming is to be determined under simulated clinical conditions.

Example 1: For an upper GI series, spot films are photo timed at 75 kVp and 400 mA. The kVp is evaluated in the manual mode at 75 kVp and 400 mA using an appropriate exposure time.

(Documentation shall include the kVp values measured, the mA station used, and the results of such measurements.)

3) Fluoroscopic Timer

The fluoroscopy timer terminates the exposure or produces an audible signal at the end of a five minute accumulative time interval.

(Documentation shall indicate that the timer was evaluated and that a conclusion was reached whether the exposure was terminated at the end of five minutes or an audible signal occurred.)

4) Exposure Reproducibility - Spot Film Mode

The ability of x-ray equipment to give reproducible exposures for multiple exposures to a single film during photo timed spot filming is to be evaluated under simulated clinical conditions. For a series of exposures to a single film/screen system, the coefficient of variation (COV) for certified x-ray equipment shall be less than or equal to 0.05.

Example 1: A facility uses a particular radiographic/fluoroscopic (R/F) room to perform fluoroscopic procedures of adults and children. For adults, 4:1 spot films are photo timed from 80 to 100 kVp on the 300 mA station. For children, 4:1 and 2:1 spot films are photo timed from 70 to 80 kVp at 400 mA. As a minimum, the phototimer is to be evaluated in the 4:1 mode on the 300 mA station at a kVp value in the 80 to 100 kVp range and on the 400 mA station at a kVp value in the 70 to 80 range. Evaluation of the phototimer for the two clinical conditions above is to be performed with a phantom which approximates the attenuation properties of an adult and child abdomen, respectively.

(Documentation will include the technique factors used in the evaluation, the in-air exposure values, and the calculated COV when necessary. A brief statement of the type of attenuation phantom used is also to be included.)

5) Fluoroscopic X-ray Field Collimation and Alignment

For under table fluoroscopic x-ray equipment, the x-ray field is to be aligned with and collimated to the effective field size of the II tube within the regulatory standards. Annual tests are to be carried out to insure that the above condition is met.

a) Maximum X-ray Field Size

(Documentation is available that indicates tests were performed demonstrating that the maximum field size of the x-ray field is confined to the II within the regulatory standards for the largest effective II size that is available. Evidence of collimation observed on the monitor will be deemed adequate.)

b) Functioning Automatic Collimation

(Documentation is available that indicates tests were performed indicating the field size adjusts automatically as the SID is varied and/or the effective field size of the II is changed.)

6) Spot Film Collimation and Alignment

a) Automatic X-ray Field Collimation

(Documentation is available that states the field size automatically adjusts to the correct portion of the spot films during the fluoroscopic procedure.)

b) Field Size Acceptable

(Documentation will indicate that the most frequently used spot film mode was tested, the size of the cassette used, and the size of the field at the film as determined from measurements obtained from the spot film.)

c) Centers Alignment Verified

(Documentation shall indicate that the center of the x-ray field corresponds to the center of the exposed portion of the film within the regulatory standard.)

7) Limits on Exposure Rates

Table top exposure rates are to be evaluated to insure that the regulatory limits are not exceeded. Documentation will indicate whether the fluoroscopic unit has a manual mode, automatic brightness control (ABC) mode, high level control (HLC) mode, the sizes of II available, and if the unit was manufactured on or before 05/19/95. (NOTE: Different limits apply for units manufactured before and after this date.)

Example 1: An older under table fluoroscopic unit with a spot film device is equipped with only a single ABC mode and a 9 inch II tube. The unit has a HLC mode. The kVp is set by the operator and the mA is driven to a value sufficient to give adequate image quality on the TV monitor. Upper and lower GI series are performed at a kVp setting in the range 80 to 100. Spot films are photo timed at 80 kVp and 4:1. With a lead absorber intercepting the x-ray beam, the exposure rate is evaluated at different kVp settings and mA values to obtain the maximum exposure rate.

(Documentation will included the maximum exposure rate and the corresponding kVp and mA values. It will included a statement as to the allowed maximum exposure rate limit and whether the unit satisfies this regulatory standard.)

Example 2: A new R/F room has been installed in a hospital. The fluoroscopic unit has both manual and ABC modes of operation, a 4, 6 and 9 inch II effective field size, and a HLC which is clinically used. For all three ABC modes, both the kVp and mA are automatically chosen. For a given patient, the specific kVp and mA values and the corresponding exposure rate depends on which ABC mode and size of II is used. With a lead absorber intercepting the x-ray beam, the exposure rate is measured in the fluoroscopic mode which will produce the maximum exposure rate. The maximum exposure rate with the HLC is to be measured also.

(Documentation will indicate the ABC or manual mode used to measure the maximum exposure rate, the value obtained, and the corresponding kVp and mA values. A statement to the effect that the unit satisfies the regulatory limits, and that the evaluation was adequate to insure that the mode used produced the maximum rate is to be included. Maximum exposure rates using the HLC are to be included.)

8) Patient Exposure Information

The Utah Radiation Control Rules require that patient exposure information be readily available to the attending physician during the fluoroscopic procedure. Such information shall be in a format such that exposure rates can be readily determined from a knowledge of the fluoroscopic kVp and mA values. An example format deemed acceptable to the Division is included. The Division recognizes that other formats are possible which would meet the intent of the regulations.

X-ray Unit:_____ Date:_____

Entrance Skin Exposure Rate (R/min)
@ table top

Table top to Intensifier distance = 25 cm,

kVp \ mA	0.5	1.0	1.5	2.0	3.0	4.0	5.0
70							
80							
90							
100							
110							

Max unit output = ___ R/min. @ ___ kVp and ____ mA
